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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,793	06/13/2000	Jiangchun Xu	210121.427C15	5630

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EXAMINER
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BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/593,793	<b>Applicant(s)</b> XU ET AL.	
	<b>Examiner</b> David J. Blanchard	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006 and 04 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19,61 and 63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,61 and 63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Claims 1-18, 20-60, 62 and 64-65 are cancelled.
2. Claims 19, 61 and 63 are pending and under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejections.

### ***Objections/Rejections Withdrawn***

5. The rejection of claim 22 under 35 U.S.C. 103(a) as being obvious over Momin et al (U.S. Patent 6,146,632, 102(e) date 7/2/1996) and Billing-Mendel et al (U.S. Patent 6,130,043, field 5/1/1998, Ids reference AC filed 1/24/2003) and Apostolopoulos et al (Vaccine, 14(9):930-938, 1996) is withdrawn in view of the cancellation of the claim.
6. The rejection of claims 64-65 under 35 U.S.C. 103(a) as being unpatentable over Billing-Mendel et al (U.S. Patent 6,130,043, 5/2/1997, Ids reference AC filed 1/24/2003) in view of Mincheff et al (U.S. Patent 6,387,888 B1, 9/30/1998, cited on PTO-892 mailed 9/2/04) and Apostolopoulos et al (Vaccine, 14(9):930-938, 1996) is withdrawn in view of the cancellation of the claims.

### ***Response to Arguments***

7. The rejection of claims 61, 19 and 63 under 35 U.S.C. 103(a) as being obvious over Momin et al (U.S. Patent 6,146,632, 102(e) date 7/2/1996) and Billing-Mendel et al (U.S. Patent 6,130,043, field 5/1/1998, Ids reference AC filed 1/24/2003) and Apostolopoulos et al (Vaccine, 14(9):930-938, 1996) is maintained.

The response filed 12/4/2006 reviews the individual teachings of the cited references, stating that Momin et al does not teach or suggest modifying the described adjuvant compositions with a polypeptide bearing any structural relationship to SEQ ID NO:113, much less a polypeptide selected so as to

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minimally comprise the specific residues 367-375 of SEQ ID NO:113. Applicant states that while Billing-Mendel teach a polypeptide sharing identity with a portion of the claimed polypeptide of SEQ ID NO:113, Billing-Mendel does not describe that the polypeptide is to be used for stimulating a Th1 cellular immune response. Applicant argues that Billing-Mendel only teaches humoral-based immune responses and as such teaches away from making compositions that contain the described polypeptide that stimulates a Th1 type immune response. Applicant argues that Apostolopoulos et al does not teach or suggest a composition comprising a polypeptide bearing any structural relationship to the polypeptide of Billing-Mendel or offer any reasonable rationale as to why a skilled artisan would be motivated to modify such a polypeptide to enhance cellular immunity.

Applicants' arguments have been fully considered but are not found persuasive. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) ("Combining the teachings of references does not involve an ability to combine their specific structures."). Thus, applicants arguments that Momin and Apostolopoulos do not specifically teach or suggest a composition comprising a polypeptide bearing any structural relationship to the polypeptide of SEQ ID NO:113 or the polypeptide of Billing-Mendel, which shares identity with a portion of the claimed polypeptide of SEQ ID NO:113 as well as applicant's argument that Billing-Mendel does not describe that the polypeptide

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sharing sequence identity with the claimed polypeptide is to be used for stimulating a Th1 cellular immune response are not found persuasive.

Regarding Applicant's argument that Billing-Mendel teaches away from using a composition comprising the described polypeptide that preferentially stimulates a Th1 type cellular immune response as claimed, Applicant is reminded that "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed... ." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Applicant also argues that there is no motivation that would have led the skilled individual to modify the immunogenic composition of Momin with the polypeptide of Billing-Mendel and administer the composition to prostate cancer patients for inducing a Th1 type immune response, when Billing-Mendel does not teach or suggest that their identified polypeptide is a T cell antigen and does not describe the T cell epitope corresponding to amino acids 367-375 of SEQ ID NO:113. Applicant states that Billing-Mendel is concerned with humoral immune responses for generating diagnostic antibodies and the skilled reviewer of Momin would not find motivation to use the polypeptide of Billing-Mendel in the adjuvant compositions of Momin, but instead would seek T-cell antigens in order that the cellular immune response to the antigens might be improved using the adjuvant compositions of Momin. Similarly, the skilled reviewer of Billing-Mendel having an interest in diagnostic markers would not be motivated to turn to Momin et al, Apostolopoulos et al or any other reference that describes methods for preferentially stimulating cellular immune responses, when Billing-Mendel is concerned solely with humoral immune responses. Applicant refers to their discovery and identification of the T cell epitope corresponding to residues 367-375 of SEQ ID NO:113 and asserts that the examiner has improperly relied on hindsight reconstruction to arrive at the claimed invention. Applicants' arguments have been fully considered but are not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the

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examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, Momin et al teach anti-cancer compositions comprising a cancer antigen and 3 D-MPL and QS21, which are preferential stimulators of a Th1 cellular immune response and Billing-Mendel et al teach the polypeptide of SEQ ID NO:36 expressed in prostate cancer tissue, which shares 100% amino acid identity with residues 299-529 of the instantly claimed SEQ ID NO:113 and Apostolopoulos et al teach that induction of a humoral immune response (i.e., Th2 response) gives poor tumor protection accompanied by little cellular immunity (i.e., Th1 response), however, when a cellular immune response is induced, this results in significant tumor protection, cytotoxic T lymphocytes and little antibody production. Therefore, one of ordinary skill in the art would have been motivated to modify the immunogenic composition of Momin et al with the prostate cancer antigen of Billing-Mendel et al and administer the immunogenic composition to prostate cancer patients for inducing a Th1-type immune response, the motivation to make the above modification is made explicit in the teachings of Apostolopoulos et al, which indicate that the induction of a Th2-type immune response or antibody response gives poor tumor protection and little cellular immunity, whereas induction of a cellular or Th1-type immune response results in significant tumor protection and little antibody production. Thus, there would be an advantage to inducing a Th1-type immune response in prostate cancer patients by administering an immunogenic composition comprising the prostate cancer antigen of Billing-

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Mendel (i.e., SEQ ID NO:36) and 3 D-MPL and QS21. While Applicants' argue that the examiner's conclusion of obviousness is based on improper hindsight reasoning, applicant is reminded that "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). As set forth in the previous Office Action and reiterated above, the instant rejection is based solely on the teachings found in the cited references and the knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made, and as such the examiner's conclusion of obviousness is proper. Further, contrary to applicants' arguments, the rejection does not rely on knowledge of the polypeptide of Billing-Mendel being a human T cell antigen.

Applicant alleges that the examiners' position, and the motivation to combine the cited references is predicated on the position that Billing-Mendel in some way discloses that their identified polypeptide is a human T cell immunogen that is to be administered to a patient for eliciting a Th1 cellular immune response and applicant states that Billing-Mendel simply does not teach this. This has been fully considered but is not found persuasive. Applicant appears to have confused the basis on which the instant rejection was set forth. The examiner agrees that Billing-Mendel does not teach that their polypeptide is a T-cell immunogen, however, this is not the basis on which the instant rejection was set forth. The rejection does not rely on any teaching found in the cited references that the polypeptide of Billing-Mendel (i.e., SEQ ID NO:36) is a T cell immunogen and in no way is predicated on such as alleged by applicant. The examiner recognizes that obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir.

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1993). The basis on which the rejection was set forth and on which it is currently being maintained is discussed supra. Specifically, one of ordinary skill in the art would have been motivated to modify the immunogenic composition of Momin et al with the prostate cancer antigen of Billing-Mendel et al and administer the immunogenic composition to prostate cancer patients for inducing a Th1-type immune response, the motivation to make the above modification is made explicit in the teachings of Apostolopoulos et al, which indicate that the induction of a Th2-type immune response or antibody response gives poor tumor protection and little cellular immunity, whereas induction of a cellular or Th1-type immune response results in significant tumor protection and little antibody production. Thus, applicant's allegation that the instant rejection is predicated on the position that Billing-Mendel in some way discloses that their identified polypeptide is a human T cell immunogen that is to be administered to a patient for eliciting a Th1 cellular immune response is a mischaracterization of the rejection, the examiners' position and as such is misplaced. The T cell epitope corresponding to amino acid residues 367-375 of SEQ ID NO:113 is a latent property of the polypeptide of SEQ ID NO:36 of Billing-Mendel. While applicant focuses on the recited property that the claimed polypeptide is a human T cell immunogen that is to be administered to a patient for eliciting a Th1 cellular immune response and the lack of such a teaching or recognition in the prior art, applicant is reminded that "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979) (Claims were directed to grooved carbon disc brakes wherein the grooves were provided to vent steam or vapor during a braking action. A prior art reference taught noncarbon disc brakes, which were grooved for the purpose of cooling the faces of the braking members and eliminating dust. The court held the prior art



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references when combined would overcome the problems of dust and overheating solved by the prior art and would inherently overcome the steam or vapor cause of the problem relied upon for patentability by applicants. Granting a patent on the discovery of an unknown but inherent function (here venting steam or vapor) "would re-move from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art." 596 F.2d at 1022, 201 USPQ at 661.). See MPEP 2145 (II).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

#### ***New Grounds of Objections/Rejections***

8. The disclosure is objected to because of the following informalities:

The examiner acknowledges applicants' amendment updating the priority information on the first line of the specification filed 12/4/2004, however, applicant needs to update the status of USSNs 09/568,100 and 09/483,672 as "now abandoned". Additionally, it is noted that USSN 09/570,737 is now allowed and should be updated with the corresponding patent number upon availability during the pendency of the instant application. Applicants' cooperation is requested in reviewing the entire disclosure for additional US Application Nos. that require updating.

Appropriate correction is required.

9. Claims 19, 61 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The claims are drawn to an immunogenic composition comprising an immunostimulant which induces a predominantly Th1-type immune response and a polypeptide comprising at least amino acid residues 367-375 of SEQ ID NO:113 and stimulates a human cytotoxic T lymphocyte response specific for SEQ ID NO:113, wherein the immunostimulant is an adjuvant or is selected from monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A and saponins. The disclosure provides insufficient written description for the broad genus of polypeptides comprising at least amino acid residues 367-375 of SEQ ID NO:113 and stimulate a human cytotoxic T lymphocyte response specific for SEQ ID NO:113. The specification discloses that the polypeptide of SEQ ID NO:113 is 553 amino acids in length and a 9-mer peptide sequence consisting of amino acid residues 367-375 of SEQ ID NO:113 (peptide P1S#10) stimulates human cytotoxic T lymphocytes and represents a naturally processed epitope of the P501S protein (i.e., SEQ ID NO:113) that is expressed in the context of the human HLA-A2 molecule (see Example 6 and pg. 125). The specification discloses that the polypeptide of the claimed invention can be an active fragment, variant, or fusion protein, wherein an active fragment includes a whole or a portion of a polypeptide which is modified by mutagenesis, addition, deletion, or substitution and where a variant is defined as comprising one or more

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substitutions, deletions, additions and/or insertions including those polypeptides having at least 70% sequence identity to the disclosed polypeptides (i.e., SEQ ID NO:113) (see pp. 80-84, for example). The transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements (MPEP 2111.03). Thus, the claims encompass an extremely large genus of polypeptides defined only by 9 amino acids out of the 553 amino acids of SEQ ID NO:113 and comprising undefined sequences at the N- and/or C-terminus of amino acids 367-375 of SEQ ID NO:113, wherein the genus of polypeptides may have very different structures and functions from the polypeptide of SEQ ID NO:113. The only identifying characteristic of the claimed genus of polypeptides is a partial structure of the human prostate tumor antigen of SEQ ID NO:113, i.e., amino acid residues 367-375 of SEQ ID NO:113. There is insufficient written description encompassing the polypeptide "comprising" at least amino acid residues 367-375 of SEQ ID NO:113 that stimulates a human cytotoxic T lymphocyte response specific for SEQ ID NO:113 because the relevant identifying characteristics of the genus such as structure or other physical and/or chemical characteristics are not set forth in the specification as-filed, commensurate in scope with the claimed invention. Conception does not occur unless one has a mental picture of the structure of the molecule, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. Further, it is not sufficient to define the polypeptide solely by its principle property, e.g., stimulating a human cytotoxic T lymphocyte response specific for SEQ ID NO:113, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required. A description of what a material does, rather than what it is, usually does not suffice. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The disclosure does not set forth a representative number of species sufficient to constitute adequate written description because the specification

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does not describe a sufficient variety of species to reflect the variation within the genus. A "representative number of species" means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).

Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, Skolnick et al (Trends in Biotechnology, 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Metzler et al (Nature Structural Biology, 4:527-531, 1997) show that any variety of single amino acid substitutions can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Mikayama et al. (Proc. Natl. Acad. Sci., USA, 90:10056-10060, 1993) teach that the human glycosylation factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (see Figure 1, in

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particular). Yet, Mikayama et al. further teach that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF activity (see Abstract in particular). Burgess et al (J Cell Biol. 111:2129-2138, 1990) show that a conservative replacement of a single "lysine" residue at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Thus, one of ordinary skill in the art could not predict the operability of any species embraced within the genus of polypeptides "comprising" amino acid residues 367-375 of SEQ ID NO:113 as identical to the disclosed polypeptide of SEQ ID NO:113.

While having written description of the polypeptide of SEQ ID NO:113 and the peptide sequence consisting of amino acid residues 367-375 of SEQ ID NO:113 (i.e., SEQ ID NO:337) identified in the specification and examples, the specification is devoid of any polypeptide "comprising" at least amino acid residues 367-375 of SEQ ID NO:113 other than SEQ ID NO:113 that qualify for the functional characteristics claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification does not provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the entire scope of the claimed invention.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

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Therefore, only the polypeptide of SEQ ID NO:113 and the peptide consisting of amino acid residues 367-375 of SEQ ID NO:113, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Blanchard  
Patent Examiner  
Art Unit 1643

DB

February 15, 2007

